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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,870	04/12/2001	Masad J. Damha	1770-206US FC	5859

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EXAMINER

EPFS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,870

Applicant(s)

DAMHA ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,7-17,36 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) 7-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,36 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claim 1 (cancelled), 2 (pending), 3-6 (cancelled), 7-17 (are withdrawn), 18-35 (cancelled), 36 (pending), 37-42 (cancelled), 43-46 are currently pending.
3. Claims 2, 36, and 43-46 are currently under examination. Claims 7-17 are withdrawn.

Drawings

4. The new and clearer version of Figure 4 provided by Applicants in the response filed 9-06-2005, is considered acceptable.

Response to Amendment

5. The rejection of claims 2, 5-6, and 19 under 35 U.S.C. 102(b)/103(a) as being anticipated by or obvious over McCormick (US Patent No. 4,760,017), is withdrawn in response to Applicant's amendment to the claims to limit the claims to an oligonucleotide for selectively preventing or modulating gene expression in a sequence-specific manner in a host; wherein said oligonucleotide is a uniformly sugar-modified oligonucleotide, based on 2'-deoxy-2'-fluoro- β -D-arabinonucleotides. The McCormick et al. reference did not teach the 2'-deoxy-2'-fluoro modification in combination with β -D-arabinonucleotides.
6. Additionally the rejection of claims 2-3, 5-6, 19, and 35, 38, and 40-42 under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (US Patent No. 5,646,126) in

view of Wilds et al. is withdrawn since the Wilds et al. reference was published after Applicant's priority date, therefore the Wilds et al. reference is not considered prior art.

7. However, the following grounds of rejection are applied as necessitated by Applicant's amendment to the claims to recite "an oligonucleotide for selectively preventing or modulating gene expression in a sequence-specific manner in a host; wherein said oligonucleotide is a uniformly sugar-modified oligonucleotide, *based on* 2'-deoxy-2'-fluoro- β -D-arabinonucleotides." Due to the ambiguity associated with the phrase "based on" as recited in the currently amended claims, the claims are now interpreted to read on a broader scope than the claims as previously presented in the last amendment to the claims.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 36, 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, and those claims depend therefrom, claims 36, 43-45, recite "an oligonucleotide for selectively preventing or modulating gene expression in a sequence-specific manner in a host; wherein said oligonucleotide is a uniformly sugar-modified oligonucleotide, *based on* 2'-deoxy-2'-fluoro- β -D-arabinonucleotides." Although Applicant's specification, at page 18, lines 18-21, mention that the invention provides "oligonucleotides *based on* 2'-deoxy-2'-fluoro- β -D-arabinonucleoside," Applicants do not

provide a definition of the phrase "based on," it is unclear if the claimed oligonucleotides consist only of 2'-deoxy-2'-fluoro- β -D-arabinonucleotides, or does this phrase encompass derivatives, wherein the 2'-deoxy-2'-fluoro- β -D-arabinonucleotides function as starting materials for synthesizing said derivatives, or wherein the oligonucleotide comprises sugar modifications on each base, and wherein at least one of those modifications include a 2'-deoxy-2'-fluoro- β -D-arabinonucleotides. Due to the ambiguity associated with the term "based on," one of ordinary skill in the art would not be reasonably apprised of the full scope of the claimed invention, in order to understand how to avoid infringement.

Claims 43-45 recites "[O]ligonucleotide according to claim 2, wherein R at the internucleotide phosphate linkage is oxygen." This phrase is vague and indefinite because there is lack of antecedent basis for this phrase in claim 2. There is no formula that recites an "R" moiety in claim 2.

Claim 46 recites "[T]herapeutic composition according to claim 4," this phrase is vague and indefinite because this phrase lacks antecedent basis since Applicants canceled claim 4.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2, 36 and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kois et al. (SEE IDS of 5-15-2002, Nucleosides & Nucleotides, Vol. 12., No. 10., pages 1093-1109), or Kois et al. (SEE IDS of 5-15-2002, Nucleic acids Symposium Series, 1993, No. 29, pages 215-216.)

The instant claims recite “an oligonucleotide for selectively preventing or modulating gene expression in a sequence specific manner in a host; wherein said oligonucleotide is a uniformly sugar-modified oligonucleotide, base on 2'-deoxy-2'-fluoro-β-D-arabinonucleotide.” Since the scope of the term “based on” as recited above is undefined in both the claim and the specification as filed, this term is interpreted broadly to include oligonucleotides that are uniformly sugar modified, wherein the oligonucleotide may comprise a 2'-deoxy-2'-fluoro-β-D-arabinonucleotide.

The phrase “for selectively preventing or modulating gene expression in a sequence specific manner in a host” is considered an intended use limitation. The following prior art is applied since the claims are not limited to the preventing or modulating of any particular gene, is not limited to a specific nucleobase sequence, and because the reference discloses oligonucleotides that are uniformly modified with 2'-deoxy-2'-fluoro-β-D-arabinonucleotide modifications, see for example, Table 1,

Art Unit: 1633

oligomers 5 and 6. The oligomers are disclosed in a 5 μ M solution in buffers A-C, absent evidence to the contrary, at least buffer B may serve as pharmaceutically acceptable carrier. In regards to the poly FMAU sequence of oligomer #5, absent evidence to the contrary, the oligonucleotide would be expected to hybridize in a sequence specific manner to the poly(A) tail of any mRNA, and thereby potentially modulate the processing of the mRNA, and thereby modulate or prevent the expression of the mRNA. Furthermore, in regards to the functional language "wherein said oligonucleotide is capable to hybridize to complementary RNA and induce (Rnase-H)-mediated cleavage thereof," recited in claim 45, since the oligonucleotide structures of Kois et al. (both references) meet all the structural limitations recited in the claims, absent evidence to the contrary, the oligonucleotides of Kois et al. would also be expected to have the same functional properties as Applicant's claimed oligonucleotides.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

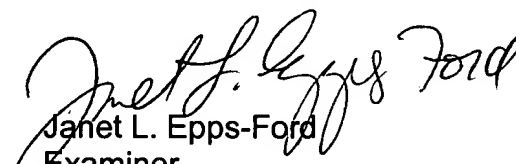
Art Unit: 1633

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Janet L. Epps-Ford
Examiner
Art Unit 1633

JLE